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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,820	04/09/2004	Kazunari Taira	04853.0059-01000	9492

22852 7590 03/02/2005

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,820

Applicant(s)

TAIRA ET AL.

Examiner

Amy H. Bowman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,9 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/763,590.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/9/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

In the amendment filed 4/9/2004, applicant has cancelled claims 1-7, 10 and 11. Claims 8, 9 and 12-15 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9 and 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is drawn to an RNA variant adopting the secondary structure of SEQ ID NO: 4, wherein said RNA variant comprises a bulge structure introduced in the region in which hydrogen bonds form between nucleotides 8 to 14 and nucleotides 73 to 79. It is unclear which nucleotides are being referred to. Nucleotides are conventionally counted in the 5' to 3' direction, however, in the instant case it is unclear whether the counting begins at the 5' or the 3' end because the nomenclature is not defined in the specification. Additionally, a ribozyme can contain flanking sequences, which would further impact the counting of the nucleotides. It is unclear whether the regions from 8 to 14 and 73 to 79 nucleotides take flanking sequences into account with regards to counting because the specification does not teach whether flanking sequences are included in the counting of nucleotides or not. Claims 9 and 14 are rejected as they

contain "nucleotides 73 to 79" and "nucleotides 8 to 14", respectively, since it is unclear how they are to be counted.

Claims 12, 13 and 14 are drawn to the RNA variant according to claim 8 and a selected chain linked thereto, wherein the chain is a ribozyme or an antisense RNA, and wherein a bulge is formed with any nucleotide of an RNA chain linked to the 3' terminus and any nucleotide of the region of nucleotides 8 to 14. It is unclear what is meant by the term "linked". The chain can be linked in a variety of ways, including covalently via a linker or non-covalently linked. Further, it is not specified how the chain is linked to the RNA variant. For example, the chain may be linked at the 3' end or the 5' end of the RNA variant. The specification does not teach what type of linkage is used or where the linkage is located at.

Additionally, it is unclear what the RNA chain of claim 14 is linked to. Claim 14 recites, "...wherein a bulge is formed with any nucleotide of an RNA chain linked to the 3' terminus..." It is unclear whether any nucleotide of the RNA chain is linked to the 3' terminus of SEQ ID NO: 4 or the 3' terminus of itself, or of another structure.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 9 and 12-15 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 8 reads on an RNA variant adopting the secondary structure of SEQ ID NO: 4, wherein said RNA variant comprises a bulge structure introduced in the region in which hydrogen bonds form between nucleotides 8 to 14 and nucleotides 73 to 79. It is unclear whether the nucleotides 8 to 14 and 73 to 79 are counted from the 5' end or the 3' end. Although nucleotides are generally counted in the 5' to 3' direction, the instant structure has not been described in a way that one of ordinary skill in the art would be able to readily envisage the claimed RNA variant. Additionally, a ribozyme can contain flanking sequences, which would further impact the counting of the nucleotides. It is unclear whether the defined regions take flanking sequences into account or not.

Claims 9 and 14 are rejected as they contain "nucleotides 73 to 79" and "nucleotides 8 to 14", respectively, since it is unclear how they are to be counted. Additionally, claims 12, 13 and 14 are drawn to the RNA variant according to claim 8 and a selected chain linked thereto, wherein the chain is a ribozyme or an antisense RNA, and wherein a bulge is formed with any nucleotide of an RNA chain linked to the 3' terminus and any nucleotide of the region of nucleotides 8 to 14. It is unclear what is meant by the term "linked". The chain can be linked in a variety of ways, including covalently via a linker or non-covalently linked. Further, it is not specified how the chain is linked to the RNA variant. For example, the chain may be linked at the 3' end or the 5' end of the RNA variant. Without description of what type of linkage is being employed, as well as where

the linkage is located between the RNA variant and the chain, one of ordinary skill in the art would not have been able to recognize what the claimed structure encompasses.

The specification does not define how the nucleotides are to be counted or offer any guidance on whether flanking sequences are considered in the counting or not. Additionally, the specification does not define what type of linkage is used or the location of the linkage between the RNA variant and the chain being instantly claimed.

The prior art teaches that ribozymes can have flanking sequences. For example, Gustafsson et al. (U.S. 6,153,428) teach ribozymes with flanking sequences complementary to domains near the 5' end (see figure 3). Kay et al. (U.S. 6,132,989) teach ribozymes containing flanking sequences that serve to anneal the ribozyme to the target RNA in a site-specific manner. The flanking sequences are taught to provide the specificity for the ribozyme. The flanking sequences are generally 4-24 nucleotides in length and are considered a part of the ribozyme sequence. The instant invention has not been described in a way that one of ordinary skill in the art would be able to envisage whether the variant contains flanking sequences or not involved with counting the nucleotides. The prior art also teaches multiple linkages to link ribozymes to various moieties. For example, Swaminathan et al. (U.S. 5,792,608) teaches ribozymes that are attached to moieties via covalent bonds, various types of linkers or non-covalent attachments. The instant invention has not been described in a way that one of ordinary skill in the art would be able to envisage what type of linkage is being instantly used or at what location the linkage is placed. Therefore, it is unclear which direction the nucleotides are to be counted in, whether counting to the region where the RNA

variant comprises a bulge would include counting a flanking sequence or not, what type of linkage is used, and where the linkage is at because the invention has not been adequately described. Therefore, it is unclear what structure would be encompassed in the instantly claimed genus, as the structure has not been sufficiently described.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

MPEP 2163 states in part, "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004)

Thus, the instantly claimed invention cannot be said to have been adequately described in a way that would convey with reasonable clarity to those skilled in the art that, as of the filling date sought, applicant was in possession of the claimed invention because the specification does not provide a description of the RNA variant that clearly describes the claimed structure.

A sequence search of SEQ ID NO: 4 has not revealed any matches that would constitute prior art. Therefore, SEQ ID NO: 4 is considered free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:30 am – 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

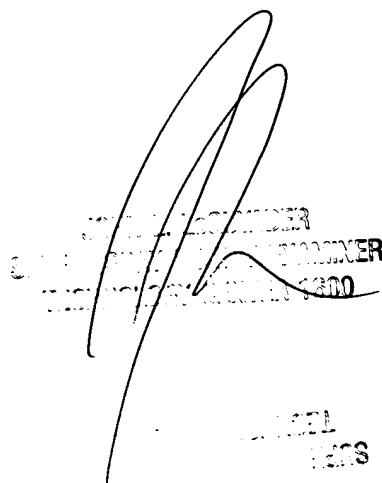
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Amy H. Bowman
Examiner
Art Unit 1635



AMY H. BOWMAN
EXAMINER
ART UNIT 1635